K083642 (pg 1/2)

MAR 6 2009

510 (k) Summary

(As required by 21 *CFR* 807.92 and 21 *CFR* 807.93)

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Dawn Sinclair Regulatory Affairs Associate Telephone: (574) 372-5023 Facsimile: (574) 371-4987 Electronic Mail: Dsincla3@its.jnj.com
DATE PREPARED:	December 5, 2008
PROPRIETARY NAME:	DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	Class III per 21 *CFR* 888.3330, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners, K062426 DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners, K023786 DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners, K003523 DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners, K002883 Biomet® Metal-on-Metal Hip Systems, K082446

DESCRIPTION:

The subject of this 510(k) consists of modifications to the Instructions for Use (IFU). The following two contraindications and potential adverse effect have been added to the IFU. DePuy Orthopaedics is making these IFU revisions to comply with a request from Health Canada, as well as to update the contents to reflect current industry practice. These are the only changes to the labeling and IFU; there are no changes to the device design.

Contraindications:

- Use is contraindicated in cases with chronic renal failure.
- Females of childbearing age are contraindicated due to the unknown effects of elevated levels of metal ions on the fetus.

Potential adverse effect:

- The potential long-term biological effects of metal wear debris and metal ion production are not known.

No changes have been made to the Indications for Use or the Intended Use of this device.

INDICATIONS AND INTENDED USE:

Indications:

The Pinnacle Metal-on-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

Intended Use:

The Pinnacle Metal-on-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Dawn Sinclair
Regulatory Associate, Regulatory Affairs
700 Orthopaedic Dr.
Warsaw, Indiana 46581

MAR 6 2009

Re: K083642
Trade/Device Name: DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA
Dated: December 8, 2008
Received: December 9, 2008

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number (if known): K083642 (pg 1/1)

Device Name: DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners

Indications for Use:

The Pinnacle Metal-on-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-on-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083642